Vena cava filters and inferior vena cava thrombosis

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Objective: **Retrievable vena cava filters (R-VCF) are a recent addition to the therapeutic armamentarium for the prevention of pulmonary embolism. However, unlike permanent vena cava filters (P-VCF), outcomes data are limited regarding complication rates.**

Methods: **This was a retrospective comparative analysis of consecutive patients undergoing placement of R-VCF vs P-VCF at Wake Forest University School of Medicine from January 2000 to December 2004. Data collected included demographics, procedural specifics, filter type, indications, and complications. Summary data are expressed as number (percentage) or mean ± SD. Continuous and categorical variables were analyzed by using *t* and Fisher exact testing, as appropriate. Four additional patients with vena cava thrombosis were also referred to our institution for treatment during the study period, all with opposed biconical VCFs (OptEase and TrapEase filters) recently placed at other facilities. This last group of patients is described but not included in the analysis.**

Results: **A total of 189 VCF (165 P-VCF and 24 R-VCF) cases were examined. No significant differences in VCF groups were observed according to age, documented hypercoagulability, or concomitant anticoagulation. Significant differences were observed according to sex (30.3% of P-VCF vs 62.5% of R-VCF patients were female), morbid obesity (4.2% of P-VCF vs 25% of R-VCF patients), active malignancy (20% of P-VCF vs 41.7% of R-VCF patients), and indication for VCF placement. Over a median follow-up of 8.5 months, no case of significant hemorrhage, no VCF migration, and four cases of vena cava thrombosis were observed. Vena cava thrombosis was observed more frequently in the presence of R-VCF when compared with P-VCF (12.5% vs 0.6%; *P* = .007). All observed vena cava thromboses were associated with severe clinical symptoms and occurred in patients who received opposed biconical VCF designs.**

Conclusions: **In our experience, both P-VCF and R-VCF can be placed safely. Among both permanent and retrievable devices, however, opposed biconical designs seem to be associated with an increased risk for vena cava thrombosis. Although causative factors remain unclear, filter design and resultant flow dynamics may play an important role, because all episodes of vena cava thrombosis occurred in patients with a single-filter design. (J Vasc Surg 2007;45:789-94.)**

Deep venous thrombosis (DVT) and pulmonary embolism (PE) are common causes of in-hospital and long-term morbidity and mortality. Venous thromboembolism (VTE) affects 104 to 117 per 100,000 persons in the United States,[1,2] with an estimated 275,000 new cases of PE accounting for approximately 50,000 deaths annually.[3,4] Anticoagulation is the first-line treatment for DVT and PE.[5] However, in certain patients anticoagulation is either contraindicated or ineffective, and in such patients PE prophylaxis using vena cava interruption filters (VCF) is the treatment of choice. Initial VCFs were designed for permanent implantation (permanent vena cava filter; P-VCF). Many patients requiring VCF have either a finite period of risk for PE or contraindications to anticoagulation that are self-limited, and removable vena cava filters (R-VCF) have been developed, approved, and promoted for use in such patients. Despite the lack of level I data supporting their use relative to P-VCF and limited follow-up experience, R-VCF have been widely adopted into clinical use since their introduction. This review examines our single-center experience with the use of both R-VCF and P-VCF, with particular emphasis on complications associated with their use.

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METHODS

Study group identification. After approval by the Institutional Review Board at Wake Forest University School of Medicine, all individuals undergoing VCF placement between January 2000 and December 2004 were identified by computerized search by using Current Procedural Terminology code 37620.

Data collection and management. Identified patient records were reviewed, including hospital charts, outpatient clinic notes, operative reports, interventional radiology reports, and noninvasive vascular laboratory records. Data abstracted included patient demographics, medical comorbidities, indication for VCF placement, procedural details, type of VCF inserted, and postinsertion complications. VCFs were classified as P-VCFs (Over-the-Wire Greenfield [Boston Scientific, Natick, Mass], Simon Nitinol [Bard, Tempe, Ariz], TrapEase [Cordis, Miami, Fla], or Vena-Tech [B. Braun Medical, Evanston, Ill]) or R-VCFs (OptEase Retrievable Vena Cava Filter [Cordis], Günther-Tulip [Cook, Bloomington, Ind], or Recovery [Bard]). Complications were defined according to the "Recommended Reporting Standards for Vena Caval Filter Place-

ment and Patient Follow-up."[6,7] Follow-up of identified patients was based on clinical records from the Wake Forest University Baptist Medical Center electronic medical record. Patients who underwent filter insertion at the study institution but had no interval assessment or follow-up in the medical record (n = 50) were excluded from analysis. Abstracted clinical data were entered into a deidentified electronic database before statistical analysis.

End-point definition. The following end points were considered to assess for complications: Vena cava thrombosis was defined as clinically apparent occlusion of the vena cava at any site and time during follow-up. Significant bleeding was defined as blood loss necessitating transfusion or prolongation of hospital stay after VCF placement. VCF migration was defined as any clinically apparent change in filter position from an infrarenal position to a perirenal or suprarenal position.

Statistical methods. Demographic and procedural data were summarized by using counts and percentages or means ± SD. Associations were evaluated for statistical significance by using the Student *t* test for continuous data and the Fisher exact test for categorical data as a result of low expected cell counts. These data were analyzed with SAS statistical software (version 9.1; SAS Institute, Inc, Cary, NC). The significance level was set at $P < .05$.

RESULTS

Study group. A total of 239 VCFs were inserted during the study period (213 P-VCFs and 26 R-VCFs). Follow-up data were available for 189 patients (including 165 P-VCF and 24 R-VCF patients), and this latter group constitutes the study sample for this report. Study sample demographics and medical comorbidities are presented in Table I. Compared with patients who had P-VCFs placed, the group receiving R-VCFs was predominantly female (62.5% vs 30.3%), had a larger proportion of patients with both malignancy (41.7% vs 20%) and morbid obesity (25% vs 4.2%), and had a lower proportion of patients with paraplegia (0% vs 26.1%). Indications for VCF placement are presented in Table II. The most frequent indication for VCF placement was VTE with a contraindication to anticoagulation in both groups (n = 117). Other indications included VTE with failure of anticoagulation (n = 12), prophylaxis in the absence of VTE in the setting of multisystem trauma (n = 49) or surgery (n = 8), and filter insertion before catheter-directed thrombolysis (n = 3). A significant relationship was observed between placement of a P-VCF vs an R-VCF and an indication for VCF insertion ($P < .001$; Fisher exact test). More specifically, P-VCFs were used nearly exclusively for prophylaxis in the setting of multisystem trauma (48 [29%] P-VCF vs 1 [4.2%] R-VCF), whereas R-VCF predominated among patients receiving filters for surgical prophylaxis (6 [25%] R-VCF vs 2 [1.2%] P-VCF) and catheter-directed thrombolysis (3 [12.5%] R-VCF vs 0 P-VCF).

Procedural data. A summary of inserted filters by type is presented in Table III. The most commonly placed P-VCF was the Greenfield Over-the Wire filter, and the most commonly placed R-VCF was the OptEase filter. Among patients receiving R-VCF, appropriate patients were assessed for device retrieval at the earliest conclusion of the period of increased risk for VTE and/or contraindication to anticoagulation. For the R-VCF group, retrieval was attempted in 11 (46%) of 24 patients and was successful in 9 patients at a median of 15 days. Planned retrieval was unsuccessful in 2 (18%) of 11 attempts because of an inability to visualize a Recovery VCF in a morbidly obese patient and termination of planned retrieval after visualization of extensive thrombus within a Günther-Tulip VCF; this latter patient was treated with anticoagulation. The remaining R-VCFs (n = 13) were intentionally left in place because of ongoing contraindications to anticoagulation

Table I. Demographics and comorbidities by filter type

Variable	*All VCF (n = 189)*	*P-VCF (n = 165)*	*R-VCF (n = 24)*
Age (y)	51.1 ± 18.9	50.8 ± 19.2	53.5 ± 17.1
Sex*			
Male	124 (65.6)	115 (69.7)	9 (37.5)
Female	65 (34.4)	50 (30.3)	15 (62.5)
Race			
White	158 (83.6)	136 (82.4)	22 (91.7)
Black	27 (14.3)	25 (15.2)	2 (8.3)
Hispanic	4 (2.1)	4 (2.4)	0 (0.0)
Active malignancy*	43 (22.8)	33 (20.0)	10 (41.7)
Coronary artery disease	56 (29.6)	47 (28.5)	9 (37.5)
Tobacco use	36 (19.1)	32 (19.4)	4 (16.7)
Defined hypercoagulable state	6 (3.2)	4 (2.4)	2 (8.3)
Paraplegia*	43 (22.8)	43 (26.1)	0 (0.0)
Morbid obesity*	13 (6.9)	7 (4.2)	6 (25.0)
Anticoagulation			
Prophylactic	69 (36.5)	65 (39.4)	4 (16.7)
Therapeutic	20 (10.6)	16 (9.7)	4 (16.7)
None	100 (52.9)	84 (50.9)	16 (66.7)

VCF, Vena cava interruption filter; *P-VCF,* permanent vena cava filter; *R-VCF,* removable vena cava filter.
*$P < .05$ for removable indicator vs demographic variable.

Table II. Indications for VCF placement

*Indication**	*All VCF (n = 189)*	*P-VCF (n = 165)*	*R-VCF (n = 24)*
VTE with contraindication to anticoagulation	117 (61.9)	106 (64.2)	11 (45.8)
VTE with failure of anticoagulation	12 (6.4)	9 (5.5)	3 (12.5)
Prophylaxis: surgical procedure	8 (4.2)	2 (1.2)	6 (25.0)
Prophylaxis: multiple system trauma	49 (25.9)	48 (29.1)	1 (4.2)
Lysis	3 (1.6)	0 (0.0)	3 (12.5)

VCF, Vena cava interruption filter; *P-VCF,* permanent vena cava filter; *R-VCF,* removable vena cava filter; *VTE,* venous thromboembolism.
Data are n (%).
*$P < .05$ for removable device vs all indications (Fisher exact test).

Table III. Vena cava interruption filter type and observed incidence of vena cava thrombosis (VCT)

Filter type	*n (col %)*	*VCT (row %)*
Permanent design		
Greenfield	162 (85.7)	0 (0.0)
Vena-Tech	1 (0.5)	0 (0.0)
Simon Nitinol	1 (0.5)	0 (0.0)
TrapEase	1 (0.5)	1 (100.0)
Retrievable design		
OptEase	13 (6.9)	3 (23.1)
Günther-Tulip	3 (1.6)	0 (0.0)
Recovery	8 (4.2)	0 (0.0)

(n = 5), progression of VTE during therapeutic anticoagulation (n = 5), or patient death (n = 3).

Follow-up and adverse events. Over a median clinical follow-up of 8.5 months (interquartile range, 15.5 months), four adverse events (all vena cava thromboses) were observed. No case of clinically apparent filter migration or significant perioperative hemorrhage was observed. All patients with vena cava thrombosis were male. Three of four vena cava thromboses occurred in patients who received retrievable filters ($P = .007$; Fisher exact test). The median time to thrombosis was 30.5 days. The US Food and Drug Administration was notified of all vena cava thrombosis cases during the preparation of this article.

The observed incidence of vena cava thrombosis with each filter design is presented in Table III. All patients with subsequent vena cava thrombosis had the same indication for filter insertion: VTE with contraindication to anticoagulation (n = 4). The opposed biconical design shared by the removable OptEase and permanent TrapEase VCF (Fig 1) was common to all filters associated with vena cava thrombosis.

Vena cava thrombosis occurred within a follow-up range of 9 to 818 days, with a median time to thrombosis of 30.5 days, and was acutely symptomatic with massive limb swelling in all patients. The only vena cava thrombosis–related fatality presented with phlegmasia cerulea dolens and abdominal compartment syndrome. This patient underwent emergent surgical venous thrombectomy, lower-extremity fasciotomies, and abdominal decompression before death. The other three cases were treated with catheter-directed thrombolysis and rheolytic thrombectomy (Angiojet System; Possis Medical, Minneapolis, Minn), with successful re-establishment of caval flow, although none had complete recanalization of the inferior vena cava sufficient for filter removal. During the study period, four additional patients with vena cava thrombosis involving VCF placed at other medical facilities were treated at our institution. All of these cases involved male patients with acute clinical symptoms of phlegmasia, and all had recently placed, prophylactic opposed biconical VCF (One OptEase and Three TrapEase) before orthopedic procedures. These cases were treated in a fashion comparable to the cases described previously and with similar results. In no case was VCF removal possible, as a result of residual caval thrombus.

DISCUSSION

This investigation details complications observed in a single-center experience with both R-VCF and P-VCF. Adverse events were uncommon, but thrombosis of the inferior vena cava was observed more commonly than expected (given the small relative number of patients undergoing R-VCF vs P-VCF insertion in this cohort) and was associated with severe clinical symptoms in all cases. Vena cava thrombosis occurred more frequently in the presence of R-VCF and was observed exclusively with a single design among both permanent and retrievable devices: the opposed biconical configuration of the OptEase and TrapEase filters.

Vena cava filters are designed to prevent fatal PE in patients with contraindications to anticoagulation and recurrent PE despite therapeutic anticoagulation. Various VCF designs exist. The gold standard filter is the stainless-steel Greenfield filter introduced in 1973.[8] The Greenfield filter has been associated with excellent protection from recurrent and fatal PE, and long-term follow-up studies with the Greenfield filter have also demonstrated low rates of adverse events, including vena cava thrombosis.[9,10] Over the past 20 years, multiple filter designs have been introduced with hopes of improving on the results of the Greenfield filter or offering greater ease of introduction. More recently, several filter designs have been introduced that allow for VCF removal at some time distant from insertion.[11-13] The concept of VCF removal is attractive given the temporary nature of the contraindication to anticoagulation and/or the period of high risk for DVT in many patients. Retrievable devices currently available in the United States include the Günther-Tulip and OptEase filters. Existing data regarding R-VCFs suggest acceptable protection against PE and a low incidence of adverse events.[13-19] Reports of adverse events after R-VCF insertion and/or retrieval exist, with reported complications including vena cava thrombosis, PE, bleeding, infection, and device migration or embolization.[20-22] No series detailing high rates of thrombosis has been previously reported.

In the current series, vena cava thrombosis was observed more frequently than expected. Cases of vena cava thrombosis involving VCF placed at our institution involved patients with VTE and contraindications to anticoagulation (two patients with DVT and bleeding complications after therapeutic anticoagulation, one patient with DVT and brain malignancy, and one patient with a history of both DVT and PE who had a filter placed before a planned hip-replacement operation). Referred cases of vena cava thrombosis after VCF placement at another institution during the study period (n = 4) all involved prophylactic filter placement before orthopedic surgical procedures. Potential explanations for the high observed rate of thrombosis include differences in device and patient selection criteria, as well as factors related to filter design. Inferior vena cava thrombosis after prophylactic filter insertion in the

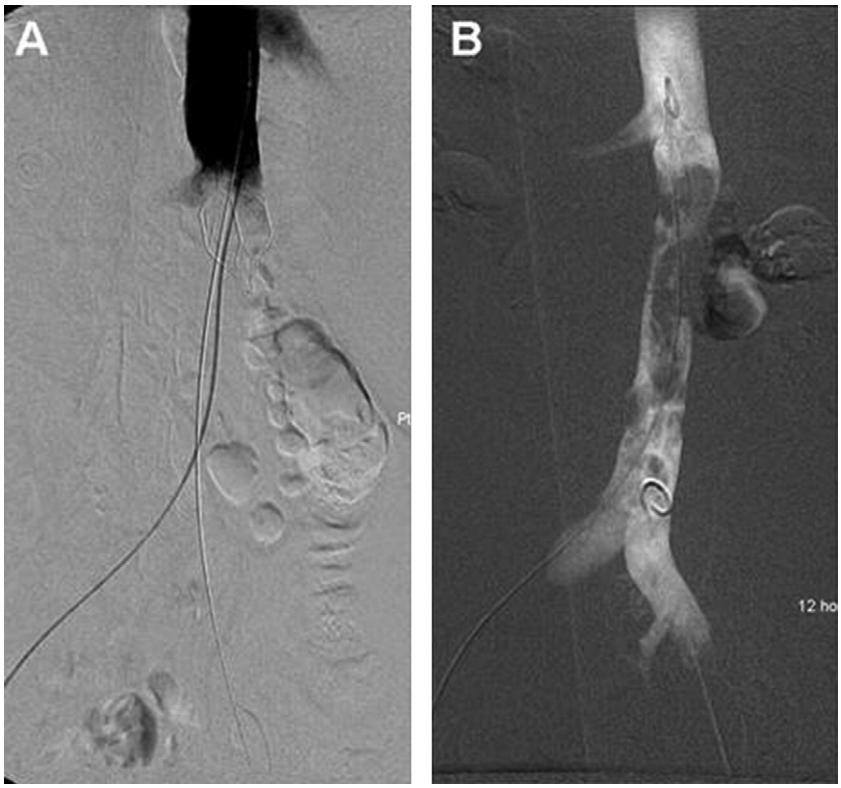

Fig 1. Vena cava thrombosis at the level of a biconical filter: (**A**) initial venography at time of catheter insertion and (**B**) partial recanalization after rheolytic mechanical thrombectomy and 12 hours of catheter-directed thrombolysis.

absence of VTE is a devastating complication that emphasizes the need for careful consideration and highly selective use for this indication. The relatively limited experience with temporary filters and the lack of data on their long-term complications (including caval thrombosis) may warrant additional imaging surveillance, especially when they are placed in a prophylactic scenario.

In this series, patients receiving P-VCF vs R-VCF differed in terms of both sex and several comorbidities (morbid obesity, paraplegia, and malignancy; Table I). Among these demographic characteristics, malignancy was more common in patients receiving R-VCF and could be a predisposing factor for thrombotic filter-related complications. However, in this series only one of eight observed vena caval thromboses occurred in a patient with active malignancy, thus making this explanation for the observed findings unlikely. In addition to hormonal factors, the female predominance in the R-VCF group is another possible explanation. However, no case of thrombosis was observed among female patients in this series. Nonetheless, a potential interaction between smaller inferior vena cava diameter and device configuration may be worthy of further investigation.

Indications for VCF insertion also differed between groups (Table II), and this may reflect a selection preference based on the previously named patient characteristics. These differences may reflect trends toward liberalization of indications for caval filtration and preferential use of R-VCF in select patient groups observed by others, particularly in the setting of multisystem trauma.[22,23] Evidence-based guidelines do not currently exist for the choice of P-VCF vs R-VCF, however, and the use of a single set of indications for caval interruption, regardless of the specific device being considered, has been advocated.[24] The predominance of R-VCF among patients experiencing vena cava thrombosis in this series further emphasizes this point and reinforces concerns over the increases in VCF use observed since the introduction of retrievable devices. Accordingly, prophylactic VCF use in the trauma population at our institution has remained selective and is limited to multisystem trauma patients with spinal cord injury, paralysis, contraindications to anticoagulation, and additional risk factors for VTE. Because the duration of increased VTE risk is temporally indistinct in this group (and in the absence of specific evidence for use of R-VCF), we have elected to use P-VCF for select, very-high-risk patients.

Inherent design differences between filters may also have contributed to the observed differences in thrombosis rates, and we believe that these differences may be directly related to filter structure more than removability per se. This is supported by the fact that all observed caval thromboses (both among devices inserted at our center and

among patients referred with vena cava thrombosis after insertion at another institution) involved the opposed biconical design (OptEase and TrapEase) VCFs. As initially suggested by the in vitro studies of Leask et al,[25] we speculate that the inverted conical design (Fig 1) of these filters marginates captured thrombus to the wall of the cava where flow is the lowest and may predispose to thrombosis. This margination effect may limit the exposure of the thrombus to intrinsic thrombolytic mechanisms, thus leading to a narrowed aperture of the patent cava that can be sequentially reduced by the centripetal accumulation of additional thrombus. A margination effect would not be operative in the single-cone design of the Greenfield, Recovery, Simon Nitinol, and Günther-Tulip filters, which should direct captured thrombus to a central location of higher relative blood flow. These hypotheses are consistent with previous investigations of the relationships between filter design, caval flow patterns, and thrombogenicity.[25-27] Alternatively, the TrapEase and OptEase designs may be more effective at capturing migrating thrombus, thus leading to a higher incidence of thrombosis. This notion would be supported if a higher incidence of clinically apparent recurrent PE were suspected or observed with the nonmarginating designs. Unfortunately, our data sources do not allow for an adequate examination of this potential explanation. Although the vena cava thrombosis rates for the biconical filter designs were remarkably high in this series (4/14, or 28.6%), others have reported much lower incidences of 0% to 1% with these devices.[15,17,28,29] Potential explanations for these discordant results include differences in patient populations, selection criteria for VCF insertion, duration of follow-up, management of anticoagulation, and technical factors.

This investigation poses interesting findings with relevance to VCF selection, but it also possesses several inherent limitations that deserve comment. This study was a retrospective investigation of complications observed after VCF placement. As such, it is subject to numerous biases and limitations in follow-up. In this cohort, vena cava thromboses were detected as the result of clinical events; lack of proscribed imaging studies to screen for this complication may have resulted in an underestimation of its incidence as a result of missed events occurring in the absence of overt clinical manifestations. After placement of P-VCF, long-term clinical follow-up was usually not scheduled with the surgical provider and consequently was more limited in this group. Many of these patients were returned to the care of their referring physicians without further contact with our health system; anticoagulation status and incidence of other thromboembolic events therefore could not be reliably determined among these patients. The R-VCF patients were more closely followed up, at least in part because of plans for timely removal of the device. These unavoidable biases could have led to underestimation of complications in the P-VCF group. This potential is somewhat mitigated by the fact that we represent the primary academic tertiary care center in our referral region, and it is unlikely that a clinically significant inferior vena cava occlusion would have been treated without referral to our center. Another potential limitation is the small number of VCF procedures reviewed, especially in the case of the R-VCF. This small number could potentially lead to erroneous overestimation of complication incidence given the small sample size. However, this seems unlikely if the complication of vena cava thrombosis is assumed to be a rare event. A final limitation that must be mentioned is the fact that the small numbers of observed complications, although worrisome, precluded intensive analyses of adverse outcomes. These combined limitations prohibit the generation of evidence-based recommendations based on these data.

Notwithstanding these limitations, this article describes a higher-than-expected incidence of complications after R-VCF placement. All observed complications were thrombotic and associated with severe symptoms. Vena cava thrombosis was limited to patients in whom the opposed biconical VCF designs were placed. These findings have led our group to be very cautious in the application of R-VCF and to eliminate use of the opposed biconical VCF designs.

AUTHOR CONTRIBUTIONS

Conception and design: MC, KJS, JA, BLC, RLG, MSE
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Writing the article: MC, KJS, JMS, MSE
Critical revision of the article: MC, JA, JMS, RLG, MSE
Final approval of the article: MC, KJS, JA, BLC, JMS, RLG, MSE
Statistical analysis: MC, JMS, MSE
Overall responsibility: MSE

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